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Description

[Cervical Cancer Screening Methods and Apparatus]

BACKGROUND OF INVENTION

[0001] Cervical cancer is the second most common cancer among women worldwide, and the leading cause of death from cancer in developing countries.

[0002] Annually, about 500.000 new cases of cervical cancer occur worldwide, and 80% of the cases do so in developing countries. These deaths are nearly 100% preventable, and early prevention is the key for the treatment of this disease.

[0003] Nowadays, prevention is reached through Papanicolaou (pap) smear. Pap screening is very easy, and only few minutes are necessary to perform it. The health care provider inserts a speculum into the vagina, holding the vaginal walls apart, and takes a sample of endocervical and cervical cells from the cervix and around cervical fornix with an instrument (spatula, cotton swab, brush,

etc.). This sample is placed on a glass slide, fixed with alcohol or cytological fixative, and sent to the pathologist for conventional analysis.

[0004] Nowadays, many types of brushes, spatulas, and cotton swabs are available to perform pap smears. However, these tests must be performed by health care providers (doctors, nurses, paramedics, ...), which implies the obligation for female patients to attend medical offices or health care centers.

[0005] Unfortunately, all these means of collecting cell samples are insufficient when women fail to comply in scheduling regular visits to health care centers.

[0006] Indeed, the major issue remains patient's compliance with the screening. On the one hand, in developed countries, many women do not have regular screening tests for various reasons: lack of time, ignorance, fear, shame, difficult mobility, lack of medical insurance. On the other hand, in developing countries, most women do not have access to health centers.

[0007] Consequently, many women are not diagnosed and get to health centers at an advanced stage of the illness. Therefore, their state requires aggressive and expensive treatments, such as invasive surgeries, radiation therapy,

chemotherapy, long-term hospitalization, and numerous medical consultations. Furthermore, in most cases, the patient's life expectancy and quality is likely to decrease whereas the cost for public health is increased.

SUMMARY OF INVENTION

[0008] The present invention relates to cervical cancer screening methods and apparatus.

[0009] The purpose of this new device is to allow women a better compliance with regular screenings: its use simplifies the pap test procedure and greatly reduces its cost, since medical offices or hospital facilities as well as qualified health personnel are no longer required to perform the endocervical and cervical cell collection. Indeed, in accordance with the present invention, the cell sample collection may be performed by women on their own, health care personnel (ex: nurses), technical health care providers (ex: lab technicians), doctors or any other trained persons. Moreover, the cell sample collection may be performed in the privacy of a home or in regions far off from health care centers.

[0010] Thus the use of this device allows to enhance women's compliance with recommended cervical cancer-screening protocols. Indeed, many women who do not comply in

scheduling regular visits to health care centers because of their busy way of life may easily perform the test on their own. Furthermore, apart from women who have access to routine tests but do not comply with them, this device can be of use for all women who, for various reasons (fear, shame, ignorance, lack of health insurance or of economic means), do not usually attend health care centers, as well as for elderly female patients with decreased mobility.

[0011] Women are thus more likely to perform regular screenings on themselves thanks to the noninvasive, simple, private and economical procedure of the invention.

[0012] Furthermore, as the sample is collected without the need for direct cervical observation or access and without the assistance of a doctor or any health care provider, this system is useful for communities whose religious or other believes prevent women from attending health care centers, since one member of these communities may be instructed to perform the sample collection and collect a great amount of samples, later on analyzed in a lab.

[0013] The present invention may also be used in mass cervical cancer prevention campaigns, since health care personnel do not need highly complex health facilities to perform the endocervical and cervical cell collection.

[0014] In addition, self-screening kits produced in accordance with the present invention may be packaged for retail sale, thus containing the device, alcohol, spray or Thin-prep®(according to every country's specificity), index card for patient's identification and directions for use. Likewise, said invention may be packaged for mass distribution (10, 50, 100, 500 units" boxes), and contain cytological fixative (spray or Thin-prep®, according to every country's specificity), index card for patient's identification and directions for use. These kits would be of great help in developing countries where shortages of doctors prevent most women from receiving screening tests.

[0015] It stands to reason that, should the test results be positive or dubious, patients will have to attend health care centers to receive a final diagnosis, according to cervix cancer-detection protocols as established in health care centers.

[0016] In developing countries, or regions far off from health care centers, in case a positive result may occur, local health organizations will be responsible for transporting patients to health care centers in order to complete the tests and achieve a full diagnosis.

[0017] The present device is easy and inexpensive to manufac-

ture, as well as easy to use and can therefore be made widely available to the consuming public.

[0018] Thus, millions of women who do not receive pap tests will have the chance to save their lives, for the benefit of the whole society.

[0019] Moreover, early detection, by allowing significant savings in the public health costs, is particularly important in developing countries where health budget is scarce. These savings may then be used on cancer or any other prevention campaign.

BRIEF DESCRIPTION OF DRAWINGS

[0020] Drawing scale: 1=1cm.

[0021] Fig. 1 & 2 are a series of cross-sectional views of the cell-collection device in accordance with an exemplary embodiment of the present invention.

[0022] *Closed position (Fig 1):* Within the plastic tube (1), the stick (3) is held underneath the nylon membrane (2), which is intact. The tip of the stick (5) is widened so as to receive the brush bristles (4). The proximal end of the stick comprises an enlargement functioning as a stop in opened position (6).

[0023] *Opened position (Fig 2):* The stick (3) is pushed inside the

plastic tube (1). The enlargement of the proximal end of the stick (6) prevents an excessive forward movement that might hurt the cervix. The tip of the stick (5) reaches the top of the distal end of the tube (1). The nylon membrane is broken (2). Brush bristles expand (4).

[0024] *Fig 3* is a cross-sectional view of the cell-collection device in accordance with an exemplary embodiment of the present invention, particularly illustrating the device positioned within the vagina (7) and in contact with the cervix (8).

[0025] *Extraction position (Fig 4):* the stick (3) is pulled back into the plastic tube (1). The brush (4) is totally inserted back in the plastic tube (1) so as to prevent vaginal contamination. The enlarged part of the stick (5) enters in contact with the narrow part of the tube in order to prevent an excessive backward movement. In order to transfer the sample onto the glass slide, the stick is pushed again as in fig 2 and the brush again exposed.

DETAILED DESCRIPTION

[0026] The present device basically comprises two parts:*A. An external part*This part is constituted by a 14 cm long per 1 cm wide plastic tube, the last 3 cm of the distal end being widened 1, 5 cm (this end being introduced into the

vagina).

[0027] The distal end of this tube is closed by an extra-thin plastic membrane.

[0028] This membrane's function is twofold: it avoids the contamination of the brush placed inside the tube while this tube is inserted within the vagina.

[0029] ·it insures the device's dispensability: the membrane being broken, it is impossible to use the device a second time.

[0030] The proximal end of the tube has an orifice in which is inserted a stick. This orifice enables the stick's movement to be stable and serves as a stop for the stick so as to prevent its exceeding the edge of the tube and hurting the patient.

[0031] *B. An internal part :* The internal part has a 16, 5 cm long per 4 mm thick internal stick, the last 1 cm of the distal end being widened 1, 3 cm. This end is bulb-shaped and comprises 1 cm long nylon bristles fixed to it. These bristles form a 3, 5 cm diameter bulb-shaped brush which will expand once breaking the membrane and collect the cell sample.

[0032] The proximal end is widened to insure easier manipulation and serve as a stop when entering in contact with to the tube to prevent stick's excessive forward movement.

[0033] In order to use correctly this device, the health care provider or the female patient herself must follow the following steps: The subject holds the tube and inserts its widest part deeply into the vagina.

[0034] Afterwards, the subject pushes the stick in order to break the tube's membrane. The brush will then enter in contact with the cervix.

[0035] The subject rotates the stick and consequently the brush. The brush bristles will rub the exocervix and part of the endocervix, thus collecting the cells.

[0036] Then the subject gently pulls the stick to insert the brush back into the tube in order to prevent vaginal contamination during the extraction of the tube.

[0037] Afterwards, the subject gently pulls the whole device out of the vagina.

[0038] Then the subject pushes the stick again in order to expose the brush and transfers the cells sample from the bristles directly into Thin-prep®or onto a glass slide where it will be fixed thanks to a cytological fixative.

[0039] Other sample processing and transportation methods can be designed. For instance, the device may be packaged for mass prevention campaigns or hospitals (10, 50, 100, 500 units" boxes), and contain cytological fixative (spray or

Thin-prep®, according to every country's specificity), index card for patient's identification and directions for use; likewise the device may be packaged for retail sale, containing alcohol, spray or Thin-prep®(according to every country's specificity), index card for patient's identification and directions for use Thinner apparatus, destined to elderly patients" comfort, can also be designed.

[0040] The whole device will be manufactured in a biocompatible material and atraumatically designed to minimize trauma to the vagina and the cervix.